PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 50 mg tablets for dogs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Enrofloxacin 50.0 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

10/20/30/50/60/100/150 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: (month/year)
Shelf life of divided tablets: 24 hours.

11. SPECIAL STORAGE CONDITIONS

Veterinary medicinal product as packaged for sale: No special precautions for storage.
Divided tablets: Store below 25^0C.
Divided tablets should be stored in the blister pack.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19994/4008

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 50 mg tablets for dogs
enrofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet B.V.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET

Floxabactin 50 mg tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:

Lelypharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 50 mg tablets for dogs

Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Floxabactin 50 mg is a white to slightly yellow, round, convex tablet.
The tablet can be divided into two equal parts.

Each tablet contains:

Active substance: Enrofloxacin 50.0 mg

4. INDICATION(S)

In dogs:

- treatment of lower urinary tract infections (associated or not with prostatitis) and upper urinary tract infections caused by *Escherichia coli* or *Proteus mirabilis*.
- treatment of superficial and deep pyoderma.

5. CONTRAINDICATIONS

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed) as the product may cause epiphyseal cartilage alterations in growing puppies).
Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.
Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.

6. ADVERSE REACTIONS

- Hypersensitivity reactions
- Alterations in Central Nervous System

Possible joint cartilage alterations in growing puppies (see 5 contraindications).
In rare cases vomiting and anorexia are observed.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use

5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 10 kg daily for:

- 10 days in lower urinary tract infections
- 15 days in upper urinary tract infections and lower urinary tract infections associated with prostatitis
- Up to 21 days in superficial pyoderma depending on clinical response
- Up to 49 days in deep pyoderma depending on clinical response

The treatment should be considered in case of lack of clinical improvement at half of the treatment duration.
The tablets may be administered directly in the mouth of the dog or simultaneously with food if necessary.

Do not exceed the recommended treatment dose.

9. ADVICE ON CORRECT ADMINISTRATION

The tablets are flavoured and are well accepted by dogs. The tablets may be administered directly in the mouth of the dog or simultaneously with food if necessary.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.

Veterinary medicinal product as packaged for sale: No special precautions for storage.
After breaking a tablet, use the remaining tablet half for the next dose.
Divided tablets: Store below 25°C.
Divided tablets should be stored in the blister pack.
Shelf life of divided tablets: 24 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals
It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the product is used. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross resistance.
Use the product with caution in dogs with severe renal or hepatic impairment.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with a known hypersensitivity to (fluoro)quinolones should avoid any contact with the product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after handling the product.
In case of contact with the eyes, rinse immediately with plenty of water.

Use during pregnancy, lactation or lay
Use during pregnancy:

Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effect. Use only according to the benefit/risk assessment by the responsible veterinarian.

Use during lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

Interaction with other medicinal products and other forms of interaction
Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.
Concurrent use of magnesium or aluminium containing substances (such as antacids or sucralfate) may reduce absorption of enrofloxacin. These drugs should be administered two hours apart.
Do not administer simultaneously with tetracyclines, phenicols or macrolides because of potential antagonistic effects.
Do not administer simultaneously with non-steroidal anti-inflammatory drugs, convulsions can occur.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdosage with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a month.

13 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste materials should be disposed of in accordance with national requirements

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION

Alu-PVC/PE/PVDC blister or Alu-PVC/PVDC blister with 10 tablets;
Box with 1 blister (10 tablets);
Box with 2 blisters (20 tablets);

Box with 3 blisters (30 tablets);
Box with 5 blisters (50 tablets);
Box with 6 blisters (60 tablets);
Box with 10 blisters (100 tablets);
Box with 15 blisters (150 tablets);

Not all pack sizes may be marketed.

Approved 14 May 2021